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EXAMINER	
SONNETT, KATHLEEN C	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/792,025	GALLOWAY ET AL.	
	Examiner	Art Unit	
	Kathleen Sonnett	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 16-20* is/are rejected.

7)☒ Claim(s) *8,14 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/6/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. **Claim 8** is objected to because of the following informalities: minor typographical error in line 3 of the claim. Omission of the word "in" from "first pivot point being in rotatable with respect to...." is suggested. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 10** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 10 recites the limitation "said inner surface" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 16-18** are rejected under 35 U.S.C. 102(b) as being anticipated by Thorne et al. Thorne et al. discloses a skin incision device comprising a casing (230) having a slot formed at a bottom surface, a cover (240) positioned on the casing that is slidable in a direction transverse to the plane of the bottom surface of the casing, a blade, an actuator that has an end cooperative with an inner surface of the cover and extends downwardly into the casing, and a carriage means. The actuator is being considered elements (320, 324, and 326) and it is cooperative with the blade from a pre-actuated to post-actuated position. The carriage means is positioned within the casing and pivotally attaches to the blade. The carriage means is being considered element (344) and is movable within the casing for guiding the blade between a pre-actuated and post-actuated position (see Fig. 20-25).

7. Regarding claim 17, the carriage element has an arcuate member (344) which is anchored and rotatably fastened to the casing through the actuator at end (342). The cam surface (any surface of 344) at the end of the acruate member is pivotally attached to the blade and is cooperative with the casing during horizontal movement of the blade.

8. Regarding claim 18, the actuator is a resilient member having a knuckle (342) formed at an end of the resilient member which is cooperative with the blade from pre-actuated to post-actuated position as it is interconnected to the blade at all times.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. **Claims 1, 2, 4-13, and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorne et al. (U.S. 5,951,582) in view of Cusack (5,314,441). Thorne et al. discloses a skin incision device comprising a casing having a slot formed at the bottom surface, a cover (240) positioned on the casing that is slidable in a direction transverse to a plane of the bottom surface of the casing, and a blade (310) pivotally positioned in the casing adjacent the slot. Thorne et al. also discloses an actuator means (320, 324, 326) anchored to the casing, the actuator means actuatable by slidable movement of the cover toward the bottom surface wherein transverse movement of the cover is converted into horizontal movement of the actuator means and the actuator means engages the blade such that at least a portion of the blade extends outward of the slot during movement between the pre-actuated and post-actuated position (Fig. 20-25). Thorne et al. fails to disclose a carriage means anchored to said casing and pivotally attached to the blade for guiding movement of the blade from pre-actuated to post-actuated position.

11. However, Cusack et al. (U.S. 5,314,441) discloses that it is old and well known in the art to include in a skin incision device a carriage means that is anchored to the casing, pivotally attached to the blade, and provides guiding movement of the blade from pre-actuated to post-actuated position. Cusack et al. further discloses that having two pivot points decreases the amount of wobble that occurs in the path of the blade as it creates an incision, which minimizes tissue damage in the areas surrounding the

incision (col. 10 lines 31-56). Adding a carriage means below the track (276) formed in casing (230) would allow for two pivot points, thereby decreasing the amount of wobble of the blade. The carriage means of Cusack et al. includes protrusion (84), channel (110), and peg (58), all of which guide movement of the blade at the end closest to the bottom surface of the casing. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Thorne et al. to include the carriage means made obvious by Cusack et al. in order to minimize tissue damage in the areas surrounding the incision.

12. Regarding claim 2, the casing has a generally open end opposite the bottom surface and the casing has sides extending upwardly from the bottom surface (see Fig. 24, Thorne et al.)

13. Regarding claim 4, the casing has a release seat (286) that retains the actuator means when the blade is in a pre-actuated position, a guide member (84 of Cusack et al.), and a capture seat that receives the actuator means at post-actuated position (end of track 276, see Fig. 25), all made integral with the inner surface of the casing. The guide member (84) is the protrusion disclosed by Cusack et al., which guides the movement of the bottom portion of the blade. Carriage means element (110) slidably contacts the bottom edge of the guide member.

14. Regarding claim 5, see Fig. 24 of Thorne et al.

15. Regarding claims 6 and 7, the modified device of Thorne et al. includes a blade with a cutting edge (77) and a retaining hole adjacent an end of the blade wherein the carriage means is cooperatively connected to the retaining hole so as to pivotally move

the razor member between the pre-actuated and post-actuated position and an elongated hole positioned adjacent an opposite end of the blade, the elongated hole being rotatably interconnected to the casing through the actuator means. The retaining hole holds the peg element (58) of the carriage means made obvious by Cusack et al. and the elongated hole is the hole (340) disclosed by Thorne et al. wherein the actuator means connects to the blade. Post element (344) is being considered the blade retainer peg, which is positioned in the elongated hole. The blade retainer peg is connected to the casing through its connection with the actuating means, which connects to the casing.

16. Regarding claim 8, the blade has a first pivot point around element (344), which is connected to the casing (230) and a second pivot point attached to the carriage means. The first pivot point is rotatable with respect to and in cam relation to the casing during movement of the blade from the pre-actuated to post-actuated position.

17. Regarding claim 9, the first pivot point is positioned over a blade retainer peg (344). Thorne et al. does not expressly state that the first pivot point is obround. However, as seen in other embodiments such as in Fig. 9, Thorne et al. shows that it is old and well known in the art to use an obround hole formed on a blade as a pivot point. It would have been obvious to one of ordinary skill in the art to employ this shape as a pivot point in other blades as well since the shape of the pivot point in the embodiment shown in Fig. 20 is not expressly stated and the blade follows an arced path in both embodiments.

18. Regarding claim 10, the actuator means comprises a top edge in abutment with the inner surface of the cover, a resilient curved member extending downwardly from the top edge and a knuckle, which is now being considered element (344) which is fixed by the casing in the end (286) of a travel pocket (276) when the blade is in a pre-actuated position and engages the blade during movement of the blade. The claim does not depend off of any claim with the limitation of a retainer peg, which was formerly being considered element (344).

19. Regarding claim 11, the casing retains the knuckle in post-actuated position.

20. Regarding claim 12, the casing further comprises a knuckle travel pocket (276) made integral with an inner surface of the casing.

21. Regarding claim 13, the casing comprises a support member made integral with an inner surface of the casing and positioned adjacent to the top surface of the casing, and in slidable contact with the actuator means during transverse movement of the cover. The support member is being considered track (276) and the walls that form it.

22. Regarding claim 19, Thorne et al. discloses the invention of claim 16 as stated in the 35 U.S.C. 102(b) rejections above. The blade has a cutting edge and a retaining hole (340) adjacent an end of the blade. The carriage means (344) is cooperatively connected to the retaining hole so as to pivotally move the razor between the pre-actuated and post-actuated position. Thorne et al. fails to disclose a blade retainer peg formed as part of the casing that is positioned in an elongated hole on the opposite side of the blade from the retaining hole.

23. However, Cusack et al. (U.S. 5,314,441) discloses that it is old and well known in the art to include in a skin incision device that has two pivot points for a blade, which provides guiding movement of the blade from pre-actuated to post-actuated position. Cusack et al. further discloses that having two pivot points decreases the amount of wobble that occurs in the path of the blade as it creates an incision, which minimizes tissue damage in the areas surrounding the incision (col. 10 lines 31-56). Adding a pivot pin below the track (276) that would sit in a hole on the blade member would allow for two pivot points, thereby decreasing the amount of wobble of the blade. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device disclosed by Thorne et al. to include the retainer peg and elongated hole (in channel 110) made obvious by Cusack et al. in order to minimize tissue damage in the areas surrounding the incision.

24. **Claims 3 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorne et al. and Cusack et al. (U.S. 5,314,441) as applied to claim 1 above, and further in view of Rutynowski et al. (U.S. 6,206,901) and Cusack et al. (U.S. 5,529,581).

25. Regarding claim 3, the modified device of Thorne et al. discloses the invention substantially as stated above, but fails to disclose a cover having a wall extending over a portion of the side of the casing, or a barb which is retained in first and second retaining slots.

26. However, Rutynowski et al. discloses that it is old and well known in the art to have an actuating means on the outside of the casing. Putting the actuating means, in

this case the cover, on the outside of the casing is merely a reversal of parts and therefore it would have been obvious to one of ordinary skill in the art to modify the device of Thorne et al. to have the cover on the outside of the casing. Cusack et al. ('581) discloses a skin incision device that has a barb on the inner member and two slots formed on the outer member. When the device is in the pre-actuated position, the barb is retained in one of the slots and when the device is in a post-actuated position, the barb is retained in the other slot (Fig. 2a-2d). The barb and retaining slot holds the blade at a set point in the casing until a threshold force is applied and stops the blade from being actuated again accidentally during disposal (see abstract). If a barb (50) is added to the inside member, now the casing disclosed by Thorne et al., the retaining slots (32, 34) would be formed on the outside member, now the cover. With the outside member being responsible for actuation, the second retaining slot, which is formed above the first retaining slot, would hold the barb while the device is in the pre-actuated position. In the post-actuated position, the barb would be held in the first retaining slot. This is necessary in order to move the cover toward the bottom surface of the casing during actuation. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Thorne et al. to include a cover on the outside of the case and a barb and retaining slot system in order to control advancement of the cover, thereby keeping the blade within the casing during pre-actuated and post-actuated positions to avoid accidental exposure to the blade.

27. Regarding claim 20, the modified device of Thorne et al. discloses the invention substantially as stated above. Briefly, Thorne et al. discloses a casing (230), a cover

(240), a blade with pre-actuated and post-actuated positions, an actuator means (320, 324, 326, 344) engaging the blade from pre-actuated through post-actuated position, and a carriage means (110, 84, 58 of Cusack '441). Thorne et al. fails to disclose the barb and retaining slot system.

28. However, as mentioned above and applying the references in the same manner, it would have been obvious to one of ordinary skill in the art to modify the device of Thorne et al. to include a barb and retaining slot system made obvious through the teachings of Rutynowski et al. and Cusack et al. ('581) in order to control advancement of the cover to protect the user from accidental exposure to the blade.

Allowable Subject Matter

29. Claims 14 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KCS

GLENN K. DAWSON
PRIMARY EXAMINER